Queen's University Belfast

Animal Welfare and Ethical Review Body (AWERB)

Annual Report 2021-22

1. Overview

The Department of Health (DOH) requires that each designated establishment maintains a viable ethical review process, which is open to continued assessment by the local inspector. The satisfactory operation of the ethical review process is a standard condition of the establishment licence held by QUB under the Animals (Scientific Procedures) Act (ASPA) 1986 (and subsequent amendments).

2. Animal Welfare and Ethical Review Body (AWERB)

2.1 The primary function of the AWERB is to review project licence applications, amendment requests and mid-term reports, and to discuss issues directly relevant to animal welfare and ethics. The specific role of the AWERB is outlined in Appendix 1. The AWERB is comprised of representatives from all relevant research areas, including Medicine, Dentistry & Biomedical Sciences, Biological Sciences, Nursing & Midwifery and Pharmacy. This ensures wide involvement of staff within the establishment, as recommended by the DOH.

2.2 At the end of the reporting period, the committee composition was as follows:

i. Academic Staff: Four representatives from relevant research areas, who are typically current project licence holders. This includes a Chair who is appointed by the QUB NCO.

ii. Post-doctoral Staff: Four postdoctoral contract researchers who are currently working within the above research areas and are routinely involved with animal research.

iii. Postgraduate Students: One PhD student who is currently working within the above research areas and is routinely involved with animal research. These committee members are rotated on an annual basis to provide invaluable experience to junior researchers.

iv. BSU Staff: The Biological Services Unit (BSU) manager and one deputy as Named Animal Care and Welfare Officers (NACWO).

v. BSU Director: Academic lead of the QUB animal facility.

vi. QUB Named Training and Competency Officer (NTCO): Academic lead for personal licensee management and training.

vii. QUB Named Information Officer: Point of contact for all PIL, PPL enquiries and main contact for DoH

viii. External Lay Representative: At least one non-QUB lay member who is appointed in conjunction with Research Governance.

viii. Named Veterinary Surgeon (NVS): Two independent veterinary surgeons appointed by the NCO.

ix. DOH Inspector: Invited to be in attendance at all AWERB meetings.

x. QUB Named Compliance Officer (NCO): Invited to be in attendance at all AWERB meetings.

2.3 During the reporting period six AWERB meetings were held (20th October 2021, 15th December 2021, 16th February 2022, 13th April 2022, 15th June 2022, 17th August 2022) at which 8-13 members were present, thus satisfying the quorum of six attending members set by the terms of reference. In addition, Strategic AWERB meetings are held to deal with additional responsibilities of AWERB. They do not deal with applications or reports. Five strategic AWERB meeting was held within the reporting period (15th September 2021, 17th November 2021, 19th January 2022, 16th March 2022, 18th May 2022). Detailed minutes of discussions and decisions are prepared and are made available for review by the DOH inspector as requested.

3. Project Licences

3.1 A project licence provides authorisation from the DOH for a defined programme of work and is typically valid for 5 years. At the end of the reporting period, there were 40 project licences issued to QUB, held by 35 different staff members, which is comparable to previous years.

3.2 At QUB, the processes involved in project licence applications include early conversations with NVS (compulsory) and AWERB Chair, NTCO, NIO and DOH inspector (as required), AWERB reviews the application and amendments are reviewed and approved by AWERB Chair (and NVS if required) before submission to DOH.

3.3 The process for project licence application is outlined in a Standard Operating Procedure. The applicant (or appropriate designate) is required to attend the AWERB meeting at which their application is considered so that they may discuss any issues or concerns directly with the committee. They are required to satisfy the AWERB that the proposed research is fully justified in relation to realistic outcomes of the project balanced against animal use. Typically, revisions are requested by the committee and final ethical approval is only granted by the Chair upon their satisfactory completion.

3.4 During the reporting period, the AWERB approved the following 7 project licence applications:

- Understanding immunity to prevent or treat infection
- Investigation of mechanisms underlying cardiovascular remodelling
- Assessment of radiobiological responses in normal tissues
- Enhancing Bone Regeneration
- Assessment of radiobiological responses in normal tissues
- Production of Novel Monoclonal
- Antibodies for Therapeutic and Diagnostic Development
- Endothelial progenitors in retinal and choroidal degeneration

3.5 A project licence provides authorisation only for a specified programme of work as defined in the original application and is normally approved for a period of 5 years. If, after issue, the project licence holder decides that they would like to modify an experimental protocol or make any other change to the licence, no matter how small, they are required to apply to the AWERB for ethical approval.

3.6 The application process is similar to that for project licence applications, with advice generally sought from and/or offered by the Chair, DOH Inspector, NVS and NACWO, prior to ethical review by AWERB.

3.7 During the reporting period, 6 project licence amendment applications were reviewed and approved. These comprised: (1) addition of a protocol to model skin infection (2) modification of protocols to add administration of therapeutic cells and clarify use of controls (3) addition of breeding a specified GM mouse strain and protocol modifications to light/dark cycle, feeding times and blood collection (4) modification of protocol to vary dosing, duration of experiment and timing of blood collection and an increase in the maximum number of animals to be used (5) addition of optional applanation tonometry to protocol (6) addition of oral gavage as a delivery route. Minor amendments were reviewed and approved by AWERB Chair and noted at following AWERB meeting. Major amendments, were reviewed by the committee prior to final review/approval by the NVS and AWERB Chair.

3.8 Mid-term reviews of all active project licences are undertaken by the AWERB at two and a half years, in which the project licence holder is required to report on:

i. project progression, including details of animal usage (licensed and Schedule 1), retrospective severity, and research outputs;

ii. project management, including details of meetings with the NACWO, BSU staff and NVS;

iii. project refinement, including plans for reducing animal use or improving animal welfare, and details of any observed adverse effects;

iv. future plans, estimating animal usage and detailing available funds for completion of the work.

3.9 The mid-term review process also involves a mandatory meeting with the NVS to discuss project progression and refinement. Only when the AWERB is satisfied that acceptable progress has been achieved, the conditions of the licence have been adhered to, and that appropriate future plans have been put in place (including funding), is ethical approval granted for project continuation. During the reporting period, 6 mid-term reviews were undertaken, all of which were approved for continuation.

4. Final Reports

4.1 In order to maintain appropriate oversight of animal research conducted under QUB project licences and to assess the balance of outputs/outcomes against animal use, the AWERB routinely review and approve all final reports before they are submitted to the DOH. Upon expiry of their project licence, holders are required to report on the same categories as detailed above in relation to mid-term review. The DOH requires a retrospective assessment of relevant projects (typically those including one of more severe protocols) which involves submission of a lay summary to be published on the Home Office website alongside the original non-technical summary approved at the start of the project. Retrospective assessments were reviewed and approved by the AWERB in parallel with project licence final reports. All final reports and retrospective assessments are considered in advance of project licence expiry and typically in parallel with the relevant renewal application.

4.2 During the reporting period, the AWERB reviewed and approved the following 9 final reports, 5 of which included retrospective assessment:

- Assessment of radiobiological responses in tumour and normal tissues
- Understanding protective immunity against bacterial infection
- Studies in diabetic eye disease
- Mechanisms underlying cardiovascular remodelling
- Extending transplant survival through enhanced T cell apoptosis
- Role of the histamine four receptor in respiratory infection

- Investigation of radiation induced bladder toxicity
- Using automated behaviour monitoring to study neurodegenerative disease in mice
- Production of novel antibodies mono and poly for therapeutic and diagnostic development

5. Additional Conditions

The DoH Inspector may impose additional conditions on individual PPLs such as annual reports of use of specific protocols. Currently, seven PPLs have additional conditions. Usually AWERB has no requirement to be involved in this process, however, one of the current four requires AWERB/ethical review of every antibody generated under the licence.

6. Use of Schedule 1

6.1. During the reporting period, AWERB acquired the function of reviewing applications for use of animals/animal tissue for educational purposes. A set of principles was agreed by AWERB and these were conveyed to staff through presentations at School Board meetings in early 2022. During the reporting period, AWERB reviewed 4 applications for use of animals for educational purposes- all were approved.

6.2 The use of animal tissue for UG and PGT projects is currently under review.

7. Other Business

7.1 Although the main role of the AWERB relates to project licence application and review, it also has other responsibilities (outlined in Appendix 1). At the main bimonthly AWERB meetings, NACWO, NVS, BSU Management and Regional AWERB Hub reports are included as standing agenda items, but time does not usually allow discussion of additional responsibilities. Therefore, it was agreed that shorter strategic AWERB meetings would be held in the interim months specifically for additional business. The following work has been undertaken by the AWERB during the reporting period:

i. AWERB Membership: Alongside the usual turnover in academic, postdoctoral and PGR representatives, we are recruiting a pool of lay members in conjunction with Faculty Research Ethics Committees and Research Governance.

ii. BSU Standard Operating Procedures: With a move to align Northern Ireland PPLs to the rest of the UK there has been a need to develop SOPs for all procedures. This has involved allocating responsible users of the procedure to draft the initial SOP followed by AWERB member review and approval. A number of SOPs are available for use and training with more added regularly. A period of training, embedding and review is required. As new PPL applications are reviewed, applicants provide any additional SOPs required for the proposed work.

iii. AWERB Hub: QUB AWERB Chair is also Chair of the NI AWERB Hub which consists of all AWERB Chairs from licenced establishments in NI. A meeting of the AWERB Hub chairs was held online on 15th December 2021. iv. The Annual NI ASPA Training Day, hosted and organised by QUB, was held online on 8th June 2022 with 196 delegates from across NI.

v. CPD: AWERB Chair attended several workshops through the year including the Annual Animals in Science Committee AWERB Hub workshop (online on 5th October 2021).

7.2 To deliver on additional responsibilities of AWERB, subgroups with an academic lead have been established related to (1) establishing and enhancing a Culture of Care, (2)

establishing a Rehoming Policy, (3) promoting good breeding practice, (4) promoting 3R's and making the AWERB more transparent and accessible.

7.3 Early in 2022, AWERB undertook a culture of care survey and listening exercise from which we developed a Culture of Care Vision (Appendix 2)

7.4 In May 2022, the inaugural Annual Culture of Care Day, supported by the Research Culture Seed Fund, was held. With approximately 70 internal and external delegates, invited speakers and exhibitors and an award for the most impactful 3R's initiative, the day was really well received and feedback was very positive. This will be an annual event.

7.5 GA passports were introduced for all genetically modified strains which will help to establish baseline mortality rates and typical husbandry/welfare requirements.

7.6 In conjunction with Research Governance and IT Services, an AWERB website was built.

Appendix 1

Role of Animal Welfare Ethical Review Body

The Animal (Scientific Procedures) Act 1986 (and subsequent amendments) gives clear guidance as to the operation of the Animal Welfare Ethical Review Body. Specifically, the AWERB has a statutory duty:

i. For the ethical review of all applications for research involving animals protected under the Animal (Scientific Procedures) Act 1986.
ii. To discuss and develop ethical advice and guidance to the Establishment Licence Holder on all matters related to animal welfare, care and use within Queen's. This shall include, but is not limited to, the standards of animal care and accommodation, including breeding stock, and the humane killing of animals.
i. Examine proposed applications for new project licences and review any amendments to existing project licences to determine local impact, how the 3Rs (Replacement, Refinement and Reduction) are being applied, and to advise the Establishment Licence Holder on the acceptability of the applications/amendments.
ii. Throughout the lifetime of projects the AWERB shall review ongoing projects ensuring continued operation against the approved project licence. Projects shall be reviewed at mid-term and on completion to enable lessons to be learnt and provide greater understanding of the 3Rs.
iii. To promote awareness of animal welfare. iv. To promote the development and uptake of the 3Rs and advise staff how to apply them.
v. To set up and regularly review procedures and protocols, including management systems, for monitoring, reporting and following up on the acquisition, welfare and proper use of animals at your establishment.
vi. To support named people, and other staff dealing with animals, on animal welfare and ethical issues.
vii. To advise on re-homing animals including appropriate socialisation.
viii. To respond to enquiries and consider advice received from the national Animals in Science Committee.
ix. To provide an annual report to the University Governance and Integrity Committee giving assurances to the University on compliance with the requirements of ASPA.

Appendix 2

QUEEN'S UNIVERSITY BELFAST

QUB Vision for A Culture of Care*

We commit to creating an animal research community that is open to discuss, share and innovate practices that will result in high animal welfare standards and a supportive environment for those involved in animal research. We recognise that animal welfare and good communication are key to producing high quality scientific results which must be our benchmark in order to justify the use of animals in our care.

We, as an animal research community, pledge to:

1. Put **animal welfare** at the heart of what we do
2. **Show compassion** to the animals and colleagues we work with
3. Comply with and **promote a 3R's framework** for designing and performing animal experiments
4. Share ideas and **create an open and honest culture** within which the giving and receiving of constructive feedback can take place
5. Maintain **clear communication** channels for raising concerns, empowering all members of the research community to take responsibility
6. **Continually review** our practices and training
7. **Communicate openly** within our organisation and externally

*This statement was based on responses to a survey of our animal research community organised by QUB AWERB.